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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/901,764      | 07/10/2001  | Clifton A. Alferness | 1759-12             | 8600             |

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EXAMINER

FOREMAN, JONATHAN M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                     |                       |
|------------------------------|---------------------|-----------------------|
| <b>Office Action Summary</b> | Application No.     | C<br>ALFERNESS ET AL. |
|                              | 09/901,764          | Examiner              |
|                              | Jonathan ML Foreman | Art Unit<br>3736      |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  
 If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  
 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  
 Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  
 Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 - 14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 - 14 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 10 July 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____. |
|--|---|

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to because Figure 4 does not label the line 5 – 5 (See [36]) describing the sectional view of Figure 5. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Regarding claim 14, the word "means" is preceded by the word "sleeve" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
  - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1 – 9 and 11, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,126,590 to Alfernness.

In reference to claim 1 and 14, Alfernness discloses a constriction device (30) (Figure 4) that constricts body tissue comprising: an elongated sleeve with opposed open ends (31 and 32) formed of expandable material (Col. 3, lines 16 – 19), when in an expanded condition receives body tissue, then when released from the expanded condition, constricts body tissue. As shown in Figure 7, the expanded condition is considered by the examiner to be prior to fastening of the attachment cord (80) during placement of the sleeve around the body tissue. When released from this expanded condition, the sleeve constricts the body tissue (Col. 3, lines 19 – 21). The sleeve of the device disclosed by Alfernness, has a portion that is visible under X ray fluoroscopy (Col. 5, lines 23 – 31).

In reference to claim 2, the sleeve disclosed by Alfernness (Figure 3) includes an outer surface and a coating of X ray opaque material on the outer surface (25). The examiner has taken coating to mean “covering” (Merriam-Webster’s Collegiate Dictionary, 10<sup>th</sup> ed), and the markers (25) in Figure 3 cover the outer surface.

In reference to claim 3, the strips of X ray material disclosed by Alfernness consisting of either platinum, titanium, or stainless steel wires (Col. 5, lines 29 – 31), are shown by Figure 3 to be along the longitudinal dimension of the sleeve.

In reference to claim 4, the sleeve disclosed by Alfernness includes a side wall extending between the opposed open ends and X ray opaque material embedded in the side wall. The root of embedded, embed, has been taken by the examiner as “to make something an integral part of” (Merriam-Webster’s Collegiate Dictionary, 10<sup>th</sup> ed). This definition will carry through to the end of this action.

In reference to claim 5, the sleeve disclosed by Alferness has a side wall that defines a longitudinal dimension of the sleeve, and wherein the X ray opaque material comprises strips of X ray opaque material (Col. 5, lines 29 – 31) embedded in the side wall along the longitudinal dimension of the sleeve.

In reference to claim 6, Alferness discloses having the X ray opaque material on the inner surface of the sleeve. Col. 5, lines 24 – 27 reads, “the material of the [sleeve] can be made radiopaque by inclusion of radiopaque markers for identification of the outside surface of the heart...”. This implies placing the markers on the inner wall of the sleeve in order to be on the outside surface of the heart.

In reference to claim 7, the strips of X ray material disclosed by Alferness consisting of either platinum, titanium, or stainless steel wires (Col. 5, lines 29 – 31), are shown by Figure 3 to be along the longitudinal dimension of the sleeve.

In reference to claim 8, the sleeve disclosed by Alferness includes a plurality of X ray opaque elements (Col. 5, lines 53 – 55).

In reference to claim 9, Alferness shows the X ray opaque elements (25) adjacent to the opening (Figure 3).

In reference to claim 11, Alferness discloses having the X ray opaque elements on the inner surface of the sleeve. Col. 5, lines 24 – 27 reads, “the material of the [sleeve] can be made radiopaque by inclusion of radiopaque markers for identification of the outside surface of the heart...”. This implies placing the markers on the inner wall of the sleeve in order to be on the outside surface of the heart.

In reference to claim 13, Alferness shows the X ray opaque elements (25) adjacent to the opening (Figure 3).

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,126,590 to Alferness as applied to claim 1 above.

In reference to claim 10, Col. 5 lines 53 – 57 teach that multiple markers can be distributed throughout the sleeve, and that by evaluating the markers in relation to each other, the performance of the tissue can be measured. Claim 10 states, “wherein the X ray opaque elements are arranged in a side-by-side relation”. Although Alferness did not specifically disclose this arrangement, it would have been obvious to one having ordinary skill in the art to place the elements in a side-by-side relation since this arrangement would have made it easy to visually see the displacement of the elements in relation to each other, therefore simplifying calculation of the heart’s performance.

In reference to claim 12, Alferness discloses having the X ray opaque elements on the inner surface of the sleeve. However, he does not disclose the preferred method of attachment. It would have been obvious to one skilled in the art at the time the invention was made to attach the elements to the inner wall of the sleeve by some sort of adhesion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703)-308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF  
August 5, 2002

  
ERIC F. WINAKUR  
PRIMARY EXAMINER